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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,031	09/29/2003	Mark A. Saab	API-020US	4506
7590 Andover-IP-Law Suite 300 44 Park Street Andover, MA 01810			EXAMINER CAMPBELL, VICTORIA P	
			ART UNIT 3763	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/674,031

Applicant(s)

SAAB ET AL.

Examiner

VICTORIA P. CAMPBELL

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-115 is/are pending in the application.
4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-18, 21, 22, 24, 25, 27, 29, 34, 91-100, 103, 104, 106, 107, 109 and 115 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 29 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/4/08, 2/15/08
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

Continuation of Disposition of Claims: Claims **withdrawn** from consideration are 19,20,23,26,28,30-33,35-90,101,102,105,108 and 110-114.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I and Species E as defined by the examiner in the reply filed on February 4, 2008 is acknowledged. Applicant has elected claims 1-34 and added claims 91-115 as belonging to Elected species E, however, the examiner does not agree with the election of claims 19, 20, 23, 26, 28, 30-33, 101, 102, 105, 108, and 110-114 as belonging to elected Species E. The various elements claimed in the above claims are not disclosed in conjunction with the portion of the specification the examiner has identified as outlining the details of Species E (Page 37, line 4-Page 40, line 2). Accordingly, claims 1-18, 21, 22, 24, 25, 27, 29, 34, 91-100, 103, 104, 106, 107, 109, and 115 are deemed to read on the elected species and will be examined as follows. Claims 19, 20, 23, 26, 28, 30-33, 101, 102, 105, 108, and 110-114 are withdrawn from consideration as being directed to non-elected subject matter.

This is the initial Office Action based on the 10/674031 application filed September 29, 2003. Claims 1-18, 21, 22, 24, 25, 27, 29, 34, 91-100, 103, 104, 106, 107, 109, and 115 as elected are currently pending and considered below.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is

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requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

3. Claim 103 recites the limitation "the exterior" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.
4. Claim 106 recites the limitation "the desired degree" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.
5. Claim 107 recites the limitation "the balloon interior" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.
6. Claim 109 recites the limitation "the tube" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

8. Applicant is advised that should claim 99 be found allowable, claim 100 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two

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claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-18, 21, 22, 24, 25, 27, 29, 34, 91-100, 103, 104, 106, 107, 109, and 115 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 6,719,773 B1 to Boucher et al in view of USPGPub 2001/0007938 A1 to Long.

Boucher et al teach the following in regards to the instant claims:

Regarding **claim 1**, Boucher et al teach a tube (10) with a fluid inlet (38) a fluid outlet (not labeled, terminal end of lumen 34), a lumen extending between the inlet and outlet (34), an inflatable and deflatable balloon element having an interior and proximal and distal ends (56), a balloon tensioning and/or wrapping device (52).

Regarding **claim 91**, Boucher et al teach an inflatable and deflatable medical balloon (56), a channel for accessing the balloon (34), a rod extending through the channel (52), and a knob (24).

Regarding **claims 2 and 92**, a working diameter of 12-25 mm is inherent to the device in order to create a large enough volume in the vertebral body.

Regarding **claims 3 and 93**, a working pressure of 200-400 psi is inherent to the device in order to effectively compact the cortical bone.

Regarding **claims 4 and 94**, Boucher et al teach a wrapped balloon diameter of 0.124 in, or 3.14 mm, which is less than 4-5 mm.

Regarding **claim 5**, wrapping device 52 is an active tensioning device

Regarding **claims 6 and 95**, Boucher et al teach in Col. 9, lines 1-6 that the balloon needs to withstand abrasion, tearing, and puncture.

Regarding **claim 7**, Fig. 6 shows expandable structure mounted on catheter body 18, and fluidly connected with lumen 34.

Regarding **claims 8 and 96**, Fig. 6 shows sealed distal end of the expandable structure 56 adjacent to stylet 52.

Regarding **claim 9**, Col. 7, lines 13-27 describe how axial movement of stylet 52 elongates and stretches the expandable element.

Regarding **claim 10**, stylet 52 is simply coupled to the distal end of the expandable element, not attached (Col. 5, lines 63-65).

Regarding **claims 11 and 97**, stylet 52 engages the distal end of the balloon element (Col. 5, lines 63-65).

Regarding **claim 12**, rotation of luer cap 24 transmits torque through coupled stylet 52 to the distal end of the expandable element 56 and wraps it into the catheter (Col. 5, line 66-Col. 6, line 50).

Regarding **claim 18**, luer cap 24 is capable of being rotated by the physician.

Regarding **claims 21 and 103**, Col. 12, lines 5-17 of Boucher et al describe creating a layered balloon to increase its toughness.

Regarding **claims 22 and 104**, expandable element 56 passes through canula 78 as shown in Fig. 11.

Regarding **claims 24 and 106**, Col. 17, lines 45-60 of Boucher et al teaches filling the cavity (80) left by deflating structure 56 with a filling material (88).

Regarding **claims 25 and 107**, removal of stylet 52 would be necessary either before or after filling with cement material so that the stylet was not permanently fixed within the vertebral body.

Regarding **claims 27 and 109**, detachment of structure 56 from tube 10 after filling with material 88 would be necessary such that the patient is also not permanently affixed to the tube and tool structure.

Regarding **claims 34 and 115**, Col. 9, lines 32-46 of Boucher et al detail many non-elastomeric materials that can be used to create the expandable structure 56.

However, Boucher et al fail to teach or disclose a spring element with particular properties as part of the balloon tensioning and/or wrapping device. Regarding these further limitations, Long teaches the following.

Regarding **claim 1**, Long teaches a spring element 73 associated with rod 78.

Compressing rod 78 toward end 80 compresses the spring and would elongate balloon 75 as spring 73 is semi-rigid.

Regarding **claim 91**, Long teaches a spring element 73 capable of applying axial or rotational forces to the balloon by means of the rod 78.

Boucher et al and Long are analogous art because they are from the same field of endeavor/problem solving area of balloon catheters. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Boucher et al and Long before him or her to modify the catheter system of Boucher et al to include the spring element of Long because the semi-rigid spring provides support to

the balloon structure (Long, Paragraph [0051]). Therefore, it would have been obvious to combine Boucher et al with Long to obtain the invention in the instant claims.

Long further teaches elements of claims 13-17 and 98-100 as described below.

Regarding **claims 13 and 98**, Long teaches a semi-rigid spring element 73 that, when compressed by rod element 78, would provide axial tensioning and elongation to balloon 75.

Regarding **claims 14, 15, 99, and 100**, Long teaches a semi-rigid spring element 73 that would provide rotational tensioning to balloon 75 if rotated by rod element 78.

Regarding **claim 16**, Long teaches a rod element 78 engaging a compressive or rotational spring element 73.

Regarding **claim 17**, Long teaches a compressive spring element 73 and a rod 78 capable of acting upon each other. Their order within the catheter shaft represents a simple rearrangement of parts and would have no affect on the function of the spring and rod combination. Thus, the claim is rendered obvious since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. USPNs 6,248,110 B1, 6,383,190 B1, and 6,582,446 B1 as well

as USPGPubs 2002/0156482 A1, 2002/0161373 A1, and 2003/0050702 A1 teach or disclose both claimed and unclaimed aspects of applicant's invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571) 270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763